

REMARKS

Reconsideration of this application in view of the above amendments and following remarks is requested. After entry of this reply, claims 22-27, 29-35 and 66-105 are pending in the application. In this Response and Amendment, claims 22, 35, and 88 are amended. No new claim is added in this Response and Amendment.

Claim Rejections – 35 USC § 103

The Examiner rejects claims 22-25, 27, 29, 30, 33-35, and 66-105 under 35 USC §103(a) as unpatentable over Ash, et al (U.S. Patent No. 5,947,953) in view of Davis, et al (WO 00/15289 A1). Applicants respectfully traverse the claim rejections under 35 USC §103(a), and submit that a prima facie case of obviousness has not been established.

With regard to independent claims 22, 35, 88, and 102, Ash describes a splittable multiple catheter assembly that has at least two fully independent catheter tubes which are initially releasably joined together. Ash does not disclose a unitary catheter tube having a distal portion and a distal end portion terminating in a distal end, a proximal portion terminating in a proximal end, an outer wall having a smooth, curved and generally convex surface without ridges or grooves, a single longitudinal bisecting wall generally bisecting the unitary catheter tube, and together with the outer wall forming a first lumen and a second lumen, each of the first and the second lumens extending longitudinally through the unitary.

Ash also discloses a catheter assembly having an outer surface that is inherently not smooth and curved and generally convex without ridges or grooves, particularly at the vessel insertion site. As shown in one representative embodiment of Ash, (figures for representative

embodiments of Ash are reproduced below), catheter 26 has an outer surface 34 defined by a rounded wall portion 36 and a generally flat side surface 38, and catheter 30 also has an outer surface 40 defined by a rounded wall portion 42 and a generally flat side surface 44. The generally flat side surfaces 38, 44 face each other, and are very close, but do not touch each other. (Ash, col. 6, lines 3-10.) Ash also discloses a splittable membrane 46 which extends longitudinally between and joins the opposite generally flat side surfaces 38, 44 of the first and second catheters 26, 30. (Ash, col. 6, lines 21-24.) In Ash, the splittable membrane 46 has a cross-sectional width at its thinnest portion w_m which is a very small fraction of the outer diameter OD1 of the catheter assembly 10 to facilitate easy tearing. (Ash, col. 6, lines 45-48.) Further, the membrane 46 has a cross-sectional length t_m which is also a small fraction of the outer diameter OD1 of catheter assembly 10. The cross-sectional length t_m also defines the distance between the generally flat side surfaces 38, 44. (Ash, col. 6, lines 54-58.) Ash thus discloses a catheter having at least two separate catheter tubes joined by a splittable membrane having a non-zero distance between the two catheter tubes defined by the parameter t_m , and a cross-sectional width defined by the parameter w_m . It is clear that the Ash catheter has an overall catheter tube outer surface inherently consists gaps or groves between the two catheter tubes.

Ash

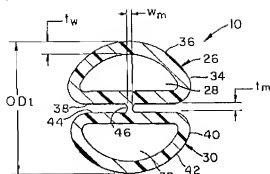


FIG. 4A

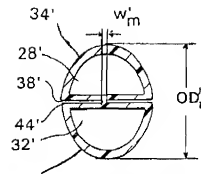


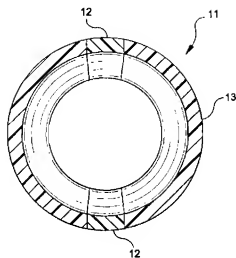
FIG. 4F

The Applicants of the present invention cite Ash in the Background section of the present application, (Para. [0011]), and clearly recognize the shortcomings of the Ash catheter design, since the need to “prevent the potential risk of leakage at the site of vessel entry” still exists in view of Ash. (Para. [0013]). The present invention provides a “smooth, curved, generally convex exterior surface of the unitary catheter 12.” “A vessel wall seals quite well around the smooth, curved exterior surface of the unitary catheter 12.” “Since the exterior of the unitary catheter 12 provides a good seal at the insertion site, the risk of blood loss around the catheter assembly 5 at the insertion site is minimized.” (Para. [0061]).

Thus, Ash does not disclose a unitary catheter tube having a distal portion and a distal end portion terminating in a distal end, a proximal portion terminating in a proximal end, an outer wall having a smooth, curved and generally convex surface without ridges or grooves, a single longitudinal bisecting wall generally bisecting the unitary catheter tube, and together with the outer wall forming a first lumen and a second lumen, each of the first and the second lumens extending longitudinally through the unitary catheter.

Further, Davis does not disclose splitting the unitary catheter tube longitudinally along the distal end portion of the unitary catheter tube, and along a length of the longitudinal bisecting wall to form a first distal end tube and a second distal end tube and bonding at least a portion of the first distal end tube to the second distal end tube to releasably attach the first and the second distal end tubes. Davis provides "a process for manufacturing a splittable tubular medical device that allows at least one preferential tear line to be formed in and to remain in the distal portion of the medical device even where the distal portion of the medical device is heated to form a tapered distal portion." The preferential tear lines 12 are stripes of materials that have different characteristics than the material that is used to form the main body portion 13 of the tube 11. (Davis, p. 9). The preferential tear line 12 is "formed by co-extruding the stripe material and the base material to form a tube or other configuration." (Davis, p.4-6 (emphasis added)). The single lumen tube of Davis is extruded in one step – with a first suitable polymer for the major portion of the tube and a second suitable polymer for the striped portion of the tube, which forms the preferential tear lines 12. Davis, p.12. Thus, the material for the preferential tear line 12 is incorporated into the tubular medical device at the same time when the major portion of the tube. Davis does not form the preferential tear line by splitting the unitary catheter tube longitudinally along the distal end portion of the unitary catheter tube, and along a length of the longitudinal bisecting wall to form a first distal end tube and a second distal end tube and bonding at least a portion of the first distal end tube to the second distal end tube to releasably attach the first and the second distal end tubes.

Davis



The tipping process disclosed by Davis involves heating a tube containing the preferential tear line, made according to the above co-extrusion process, on a mandrel, and in a die having an interior molding surface according to the desired shape of the distal portion of the tube. The mandrel and the die are then brought together so that the distal edge of the mandrel engages the tapered distal portion of the die. This action cleanly forms a smooth and uniform tapered distal portion for the tube. (Davis, p.12). Davis requires the material for the preferential tear lines and the main portion of the tube to have similar melt and flow properties. One material would not flow substantially into the other material when the materials are co-extruded into a tube or when the distal portion of the tube is tipped. "This ensures that the materials adhere to one another yet preserves the integrity of the preferential tear line along the distal portion of the tube." (Davis, p.5). Thus, the advantage of Davis over a prior art tear line produced by a skiving process, or a tear line formed by particular molecular orientation of the tube material, is the formation of a

preferential tear line that would maintain its integrity during the tipping process described above. The selection of materials for the preferential tear line and the main tube portion to have similar melt and flow properties, and the co-extruding the materials to form a tube having at least one stripe of material for the preferential tear line that extend substantially completely through the radial dimension of the tube from the inner surface to the outer surface are essential for the formation of the Davis preferential tear line. However, nowhere in Davis discloses splitting the unitary catheter tube longitudinally along the distal end portion of the unitary catheter tube, and along a length of the longitudinal bisecting wall to form a first distal end tube and a second distal end tube and bonding at least a portion of the first distal end tube to the second distal end tube to releasably attach the first and the second distal end tubes.

In view of the above, Ash and Davis, either alone or in combination, do not disclose all the elements of independent claims 22, 35, 88, and 102. It follows that Ash and Davis, either alone or in combination, do not disclose all the elements of dependent claims 23-25, 27, 29, 30, 33, 34, 66-87, 89-105.

Additionally, the teaching of Davis are not combinable with Ash. The Ash method forms two separate catheter tubes and then releasably attaching the two catheter tubes with a splittable membrane. The catheter tubes then may be partially split. The Davis method, on the other hand, forms the preferential tear line in one co-extrusion process. The co-extrusion process of Davis thus can not be combined with Ash when two separate catheter tubes are already formed and separated. Even the tipping process of Davis acts on a single tube that contains the pre-formed preferential tear line. It is also not combinable with Ash to bond or releasable attach separate catheter tubes together.

The Examiner rejects claims 31 and 32 under 35 USC §103(a) as unpatentable over Ash, et al (U.S. Patent No. 5,947,953) in view of Davis, et al (WO 00/15289 A1) as applied to claim 22 above, and further in view of Melsky et al (U.S. Patent No. 5,704915). Applicants respectfully traverse the claim rejections under 35 USC §103(a), and submit that a prima facie case of obviousness has not been established.

In view of the above, Ash and Davis, either alone or in combination, do not disclose all the elements of independent claim 22. It follows that Ash, Davis and Melsky, either alone or in combination, do not disclose all the elements of dependent claims 31 and 32.

Applicants respectfully request that the Examiner withdraw the rejections of claims 22-25, 27, 29, 30, 33-35 and 66-105 under 35 USC §103(a) as unpatentable over Ash in view of Davis, and claims 31 and 32 under 35 USC §103(a) as unpatentable over Ash in view of Davis and further in view of Melsky.

CONCLUSION

In light of the above amendments and remarks, Applicants submit that pending claims 22-27, 29-35 and 66-105 are allowable, that the application is in condition for allowance, and requests that the Examiner issue an early notice of allowance. The Examiner is invited to call the undersigned attorney to advance prosecution of this application.

The Commissioner is hereby authorized to charge any deficiency or credit any overpayment of the fees associated with this communication to Deposit Account No. 02-2555.

Respectfully submitted,

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Shawn Li
Registration No. 58,132

Blank Rome LLP
One Logan Square
18th & Cherry Streets
Philadelphia, PA 19103
215-988-6993